REMARKS

Reexamination and reconsideration in light of the foregoing amendments and following remarks is respectfully requested.

I. AMENDMENTS

Claim 13 is currently pending.

Claim 13 has been further amended to recite that the dose of the COX-2 inhibitor ranges from about 5 mg. to about 1,000 mg. per day.

The Applicant avers that the amendment to the claim presented *supra* are supported by the specification as filed and published (see, for example, Claim 5 as originally filed and Examples 1, 2, 4, and 6 – 8) and do not add new matter. The Applicants respectfully request entry of the claim as amended

II. THE CLAIM AS AMENDED IS PATENTABLE UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claim 13 stands rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement. The Examiner maintains that the specification does not reasonable provide enablement for the claimed bioavailable pharmaceutical composition comprising a therapeutic quantity of a COX-2 inhibitor having an IC50-WHMA COX-2/COX-1 ratio ranging from about 0.23 to about 3.33 with reduced gastrointestinal and cardiovascular toxicity. The Applicant respectfully disagrees.

Claim 13 has been amended supra to recite that the dose of the COX-2 inhibitor ranges from about 5 mg. to about 1,000 mg. per day. The Applicant maintains that this amendment describes the metes and bounds of what the inventor considers as the invention. The amended claim identifies both the active compound as well as the dose range required to produce the desired effect. The Examiner's attention is directed to Claim 5 as originally filed and Examples 1, 2, 4, and 6 – 8 for enablement of this claim.

As such, the Applicant submits that the application has been enabled under 35 U.S.C. § 112, first paragraph and respectfully requests withdrawal of the rejection of Claim 13.

III. THE CLAIM AS AMENDED IS PATENTABLE UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claim 13 stands rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Applicant respectfully disagrees.

Claim 13 as amended specifically identifies the conditions for treatment according to the claimed method (osteoarthritis, rheumatoid arthritis, or acute pain); identifies the active moiety (isoalpha acid); defines a dose range for administration (the dose of the COX-2 inhibitor ranges from about 5 mg to about 1,000 mg per day); and defines the COX-2 inhibitor having an IC50-WHMA COX-2/COX-1 ratio ranging from about 0.23 to about 3.3.

The Examiner's attention is directed to Claim 5 as originally filed and Examples 1, 2, 4, and 6 – 8 for descriptive support and enablement of the amended claim. As such, the Applicant submits that the application has been enabled under 35 U.S.C. § 112, second paragraph and respectfully requests withdrawal of the rejection of Claim 13.

IV. CLAIMS 13 AS AMENDED IS PATENTABLE UNDER 35 U.S.C. § 102(B)

Claim 13 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Rigby et al (US 3,354,219; hereinafter "Rigby") as evidenced by Medicinenet.com and About.com. The Examiner states that Rigby teaches that hot water, NaOH, and hops are boiled for two hours and that the reference additionally noted that KOH can be used instead of NaOH.

The Examiner further states that Medicinenet makes it clear that acute pain comes on quickly and thus reads on anyone since anyone can have acute pain. The Examiner goes on to state that About.com makes it clear that standardized extracts have been processed to contain a specific amount of a compound but as seen in Rigby once the extract is reacted with KOH a specific amount of iso-alpha acids are formed.

The Applicant respectfully disagrees with the Examiners assertion of Claim 13, as amended, being anticipated by Rigby et al (US 3,354,219; hereinafter "Rigby") as evidenced by Medicinenet.com and About.com.

The reference art cited must teach each and every element of a claim to be considered anticipatory to that claim and the Applicant maintains that Rigby as evidenced by Medicinenet.com and About.com fails to teach the elements of the claim.

Rigby is merely directed to a method for producing an isohumulone concentrate. Rigby neither teaches nor suggests that the isohumulone concentrate can be used to treat any condition, let alone osteoarthritis, rheumatoid arthritis, or acute pain as in the instant case. Furthermore, Rigby neither teaches nor suggests the dose of the COX-2 inhibitor having ranges from about 5 mg. to about 1,000 mg. per day nor defines the COX-2 inhibitor having an IC50-WHMA COX-2/COX-1 ratio ranging from about 0.23 to about 3.3.

Medicinenet.com merely provides a definition of acute pain while About.com defines a standardized extract and the Applicant maintains that neither reference corrects the deficiencies of Rigby as to currently amended Claim 13.

As such, the Applicant submits that Rigby as evidenced by Medicinenet.com and About.com is not anticipatory to Claim 13 and respectfully request withdrawal of the 35 U.S.C. § 102(b) rejection of Claim 13.

V. CLAIMS 13 AS AMENDED IS PATENTABLE UNDER 35 U.S.C. § 103(A)

Claims 13 stands rejected under 35 U.S.C. § 103(a) as being anticipated by Rigby et al (US 3,354,219; hereinafter "Rigby") as evidenced by Medicinenet.com and About.com.

The Examiner states that Rigby teaches that hot water, NaOH, and hops are boiled for two hours and that the reference additionally noted that KOH can be used instead of NaOH.

The Examiner further states that Medicinenet makes it clear that acute pain comes on quickly and thus reads on anyone since anyone can have acute pain. The Examiner goes on to state that About.com makes it clear that standardized extracts have been processed to contain a specific amount of a compound but as seen in Rigby once the extract is reacted with KOH a specific amount of iso-alpha acids are formed.

The Applicant respectfully disagrees with the Examiners assertion of Claim 13, as amended, being anticipated by Rigby et al (US 3,354,219; hereinafter "Rigby") as evidenced by Medicinenet.com and About.com.

The Applicant maintains that the reference art cited neither teaches each and every element of a claim nor provides any motivation to combine the references to produce the instant invention and is therefore not obvious.

Rigby is merely directed to a method for producing an isohumulone concentrate. Rigby neither teaches nor suggests that the isohumulone concentrate can be used to treat any condition, let alone osteoarthritis, rheumatoid arthritis, or acute pain as in the instant case. Furthermore, Rigby neither teaches nor suggests the dose of the COX-2 inhibitor having ranges from about 5 mg to about 1,000 mg per day nor defines the COX-2 inhibitor having an IC50-WHMA COX-2/COX-1 ratio ranging from about 0.23 to about 3.3.

Medicinenet.com merely provides a definition of acute pain while About.com defines a standardized extract and the Applicant maintains that neither reference corrects the deficiencies of Rigby as to currently amended Claim 13.

As such, the Applicant submits that Rigby as evidenced by Medicinenet.com and About.com is not obvious to amended Claim 13 and respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of Claim 13.

VI. CONCLUSION

On the basis of the foregoing remarks and amendments, Applicants respectfully submit that amended Claims 13 is in condition for allowance. Passage to issue is respectfully requested.

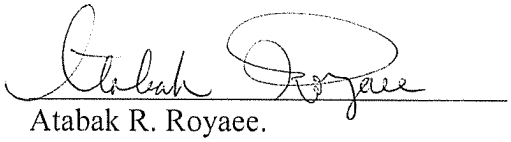
If there are any questions regarding these remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

A Request for a Three (3) Month Extension of Time, up to and including February 22, 2009 is included herewith. Pursuant to 37 C.F.R. § 1.136(a)(2), the Examiner is authorized to charge any fee under 37 C.F.R. § 1.17 applicable in this instant, as well as in future communications, to Deposit Account 50-1133.

Furthermore, such authorization should be treated in any concurrent or future reply requiring a petition for an extension of time under paragraph 1.136 for its timely submission, as constructively incorporating a petition for extension of time for the appropriate length of time pursuant 37 C.F.R. § 1.136(a)(3) regardless of whether a separate petition is included.

Respectively submitted,

MCDERMOTT WILL & EMERY LLP



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